OMICS International
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Asmaa A El-Zaher et al., J Anal Bioanal Tech 2015, 6:4
http://dx.doi.org/10.4172/2155-9872.S1.021

6th International Conference and Exhibition on
Analytical & Bioanalytical Techniques
September 01-03, 2015 Valencia, Spain

Validated liquid chromatographic method for simultaneous determination of metformin, pioglitazone, sitagliptin, repaglinide, glibenclamide and gliclazide: Application for counterfeit drug analysis

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A rapid, precise and selective RPLC method was developed for the simultaneous determination of the widely used oral anti-diabetic; metformin hydrochloride (MTF), along with some of the most commonly prescribed oral anti-diabetic medications representing different pharmacological classes, namely; sitagliptin phosphate (SIT), pioglitazone hydrochloride (PGZ), gliclazide (GLZ), glibenclamide (GLB) and repaglinide (RPG), in bulk, laboratory prepared mixtures and their pharmaceutical formulations. The developed method is recommended for application in the quality control of the herbal anti-diabetic products to detect possible counterfeits. The chromatographic separation carried out using gradient elution mode with acetonitrile: 0.05 M potassium di hydrogen phosphate (MKP) and 0.01 M sodium octane sulphonate (SOS) (pH 3.55) at a flow rate of 0.85 ml/min on a Kromasil 100- C18, (30 x 0.4 cm, 10 µm) at a temperature of 40°C. UV detection carried out at 220 nm. The method validated according to ICH guidelines. Linearity, accuracy and precision were satisfactory over the concentration ranges of 0.05-205 µg/ml for MTF, at 0.05-100 µg/ml for PGZ, GLB and SIT, at 0.1-100 µg/ml for RPG and at 1-100 µg/ml for GLZ. The correlation coefficients were > 0.99 for all analytes. Limits of quantification (LOQs) found to be 0.002, 0.003, 0.009, 0.012, 0.007 and 0.024 µg/mL for MTF, SIT, PGZ, GLZ, GLB and RPG respectively. The method was successfully applied for the determination of each of the studied drugs in their synthetic mixtures and pharmaceutical dosage forms. The developed method is specific and accurate for the quality control and routine analysis of the cited drugs in their pharmaceutical preparations.

Biography

Asmaa A El-Zaher has completed her PhD at Cairo University in 1999 and teaches pharmaceutical and medicinal chemistry in Cairo, Ain Shams, Misr International Universities in Egypt and Umm Al-Qura University in Saudi Arabia. She is specialized in drug analysis. She supervised more than 12 master and PhD awarded thesis and about the same number in progress. She has been awarded for her international publication for more than 4 times by Cairo University. She has published more than 25 papers in reputed journals and more than 10 conference abstracts. She has been serving as reviewer for many reputable journals.

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